



Manufacturers & Exporters of Pharmaceuticals  
www.deltaenterprises.org

QUALITY CONTROL DEPARTMENT

Page 1 of 1

THE DRUG & COSMETIC ACT, 1940 & THE RULES THERE UNDER FORM-39(RULE 150-E(F))

FINISHED PRODUCT CERTIFICATE OF ANALYSIS

Product Name : DELGRA 120	A.R. No. : F/521/12
Packing : 10x10 TAB	Rel. Dt. : 03-08-2012
Generic Name : SILDENAFIL CITRATE TABLETS 120MG	T.R. Slip No. : CBPTP12523
Product Code : DELG03	T.R. Slip Dt. : 31-07-2012
Batch No. : T-215001	Analysis Date : 03-08-2012
Actual Batch Size : 54000 TAB	
Packing Batch Size : 54000 TAB	
Sample Size : 50 TAB	
Released Qty : 54000 TAB	
Remarks : pass	
Mfg. Dt. : JUL-2012	Location : GORWA01
Exp. Dt. : DEC-2014	Make : CENTURION
Test Packing : 50 TAB	
Mfg. Lic No. : G/25/1325	
Test As Per : IH	

Sr. No.	Test	Result	Specification
1	DESCRIPTION	A blue colored, diamond shaped, biconvex, plain on both side, film coated tablet.	A blue colored, diamond shaped, biconvex, plain on both side, film coated tablet.
2	IDENTIFICATION	Complies.	Complies as per IHS
3	AVERAGE WEIGHT (TABLETS)	523.2 mg	527.880 mg $\pm$ 5 %
4	UNIFORMITY OF WEIGHT	Complies.	Complies Within $\pm$ 5 %
5	HEIGHT	14.53mm	14.60 mm $\pm$ 0.1 mm
6	THICKNESS	5.01mm	5.00 mm $\pm$ 0.2 mm
7	DISINTEGRATION TIME	06' 39" Minutes in : Water. Medium at 37°C	NMT 30 Min
9	ASSAY	104.6 %	Each film-coated tablet contains. Sildenafil Citrate eq. to Sildenafil 120 mg [Limit : 90% TO 110%]
	DISSOLUTION	92.30%	NLT 70.0%



Conclusion : The above sample complies as per IH  
In the Opinion of the undersigned the sample referred to above is of Standard quality as defined in the Act and the Rules made thereunder for the reasons given above.

Analysed By  PPR QC CHEMIST	Approved By  KRISHNA PANCHAL Q.C IN CHARGE
--------------------------------------	---